APPENDIX C

HUMAN RESEARCH MASTER PROTOCOL

Proposed JSC Reduced Gravity Program Research

Tentative Flight Dates _____

NOTE: All headings or statements in bold are to be included in the protocol and in the order listed.

1. TITLE

2. ORGANIZATION CONDUCTING THE RESEARCH

   Normally the institution with which the Principal Investigator (PI) is affiliated.

3. INVESTIGATORS

   A. List all investigators starting with the PI, their addresses, and phone numbers. Attach curriculum vitae for each investigator at the end of the protocol.

   B. List technical personnel who will aid in and/or conduct the research. Attach qualifications at the end of the protocol. The Committee is interested in the qualifications of the technical staff that will be interacting with the test subjects because they will be operating equipment or performing procedures on them.

4. HYPOTHESIS(ES)

   The hypotheses should be clearly and succinctly stated. The Committee must consider scientific merit as a factor in weighing risks vs. benefits. This summary should abstract the details to be included in Section 5.

5. PURPOSE OF RESEARCH

   A. Historical Background

      A brief background statement should trace the development of key factors or principles which led to the formulation of hypothesis. Reference to pertinent scientific literature is essential.

   B. New Information Expected

6. JUSTIFICATION FOR USE OF HUMAN SUBJECTS

   Explain why humans are a necessary part of the study.

7. STUDY PLAN AND SCHEDULE

   Give an overview of what will be accomplished during preflight training/base-line data collection sessions, in-flight experimentation, and postflight data acquisitions. For example, familiarization with the concepts of the experiment, procedures to be learned, equipment to be used, data collection, etc.

   A. Dates/Duration

      Give as close an approximation as possible.

   B. Place(s) of Training Test

   C. Subjects

      Provide names, dates of physicals and physiological training, and date consent form(s) signed for each subject.

8. EXPERIMENTAL PROTOCOLS AND EQUIPMENT

   This section contains some of the most important information used by the Committee. It is from this section that the Committee may identify potential problems that might be overlooked by the investigators. Experience has shown that incompleteness of this section is one of the major reasons for IRB nonapproval.

   A. Prefight Training and Baseline Data Collection

      Describe preflight training and baseline data collection in terms of step-by-step procedures and equipment used. All equipment must be identified. In those instances where any hardware is used for training or ground-based testing, the PI is responsible for providing detailed descriptions and hazard analysis as an attachment to the protocol submittal. The PI is also responsible for maintaining configuration control of the hardware to prevent any modifications that would compromise the hazard analysis. Inspection records must be provided to assure the hardware configuration and to assure adherence to test requirements and procedures. Functional test and checkout of equipment utilizing non-flight crew personnel is required. All equipment, whether commercial, modified commercial, or custom designed, used for fit and functional testing, must be inspected by the JSC Safety Office. These results, together with equipment safety certification, must be submitted by the PI to the IRB prior to flight.

B. In-flight Activities

List step-by-step procedures and equipment used, approximate duration of the testing, how many flight personnel are necessary, and how many times the experiment will be performed.

C. Postflight Activities

If postflight testing of flight personnel is necessary, note how many times the test will be done, when, where, and what procedures and equipment will be used.

9. HAZARD ANALYSES AND SAFETY PRECAUTIONS

Detail the conceivable hazards that might be encountered during the study and the precautions that will be taken to avoid them. For research involving animal handling, list precautions employed for minimizing zoonoses.

A Preflight Activities
1. Potential Hazards
2. Protection to Minimize Risks
3. Assessment of Residual Risks

B. In-flight Activities
1. Potential Hazards
2. Protection to Minimize Risks
3. Assessment of Residual Risks

C. Postflight Activities
1. Potential Hazards
2. Protection to Minimize Risks
3. Assessment of Residual Risks

10. POSSIBLE INCONVENIENCES OR DISCOMFORTS TO SUBJECTS

List additional factors that do not fall into the category of hazards, but that should be considered.

11. EXTENT OF PHYSICAL EXAMINATIONS

In many cases, reliance on the annual physical examination for flight personnel is all that need be stated. If a special physical examination or special test is required, describe it and state why it is needed.

12. AVAILABILITY OF A PHYSICIAN AND MEDICAL FACILITIES

State if a flight surgeon and/or facilities will be required during preflight, flight, or postflight.

13. REQUIRED STATEMENTS FOR HUMAN RESEARCH SUBJECTS

A. "**The subject will be free to withdraw from the research at any time**. Except . . . (Describe any circumstances under which it would be hazardous or unwise to do so.)"

B. "The identity of human subjects will not be released to the general public without his or her consent unless specifically required by law."

C. "There will be no additional wage, salary, or other remuneration of any form paid, given, or in any manner delivered to the test subjects of this investigation where the subjects are NASA employees, NASA contractor employees or independent contractors, and the terms of the contracts with NASA provide for participation as subjects in approved experiments."

D. "The human research subjects are NASA employees, NASA contractor employees or independent contractors, and the training/testing is part of their employment or contractual circumstances. Therefore, NASA is responsible for compensation for injury, death, or property damage to the extent required by the Federal Employees Compensation Act or the Federal Tort Claims Act."

14. REQUIRED ATTACHMENTS

A. Include information concerning human research to be communicated to the subjects in the course of obtaining their informed consent. **Along with a signed consent form, attach a summary signed by the subject describing in layman's terms the procedures the subject will undergo**.

Include the following statement in the summary: "Since the KC-135 is considered to be a public aircraft within the meaning of the Federal Aviation Act of 1958, as amended, and as such does not hold a current airworthiness certificate issued by the Federal Aviation Administration (FAA), any individual manifested to board the KC-135 should determine before boarding whether his/her personal life or accident insurance provides coverage under such condition."

B. If required, attach the appropriate JSC Consent Form to be employed (see Appendix 4). Specify the appendix designation in this section. If not required, so state.

C. Attach a copy of the **Approval by the PI's Institutional Review Board** (Human Research or Ethics Committee). Specify the appendix designation.

D. Attach a copy of the **Institutional Safety Authority's** most recent certification of all related equipment. Specify appendix designation(s).

E. If external radiation sources or radionuclides are employed, their use must have the approval of the JSC Radiation Safety Committee. Attach a copy of the **Approval of the JSC Radiation Safety Committee**. Specify appendix designation.

F. Research use of drugs for indications not in the package insert is subject to Food & Drug Administration (FDA) restrictions. Prior to shipping the drugs in interstate commerce, either the sponsor (the manufacturer) or the clinical investigator must file form **FDA 1571, Notice of Claimed Investigational Exemption for a New Drug (IND)** with the FDA. The FDA regulations also require each clinical investigator who uses investigational drugs in humans to file with the sponsor of the investigational new drug (IND) either form **FDA 1572** or form **FDA 1573, Statement of Investigation**. Attach copies of the forms that have been filed and proof of submission date (e.g., certified mail receipt) or a statement of not having received a written reply from the FDA 60 days after the submission of forms. Attach a copy of the FDA reply, if it has been received.

This page intentionally blank